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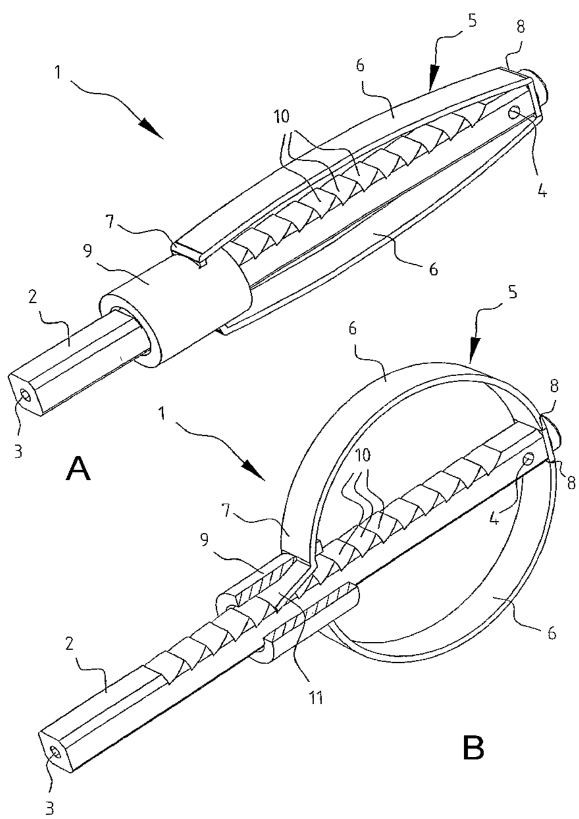
(54) Title: EXPANDABLE IMPLANT FOR TREATING FRACTURED AND/OR COLLAPSED BONE



(57) Abstract: The present invention relates to an expandable implant for treating fractured and/or collapsed bone, comprising a tube carrying an expansion member comprising expansion means for expanding the implant and creating a cavity, wherein said tube comprises at least one outlet for discharging a fill material within the created cavity, said implant comprising means for converting an axial movement of said tube relative to the expansion member in a controlled transverse movement of the expansion means.

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EXPANDABLE IMPLANT FOR TREATING FRACTURED AND/OR COLLAPSED BONE

The present invention relates to an expandable implant for treating fractured and/or collapsed bone. The invention in particular relates to an expandable implant for treating and stabilizing vertebral body fractures.

Vertebrae are the bones of the spine. A typical vertebra consists of two essential parts, i.e. an anterior segment, the body, and a posterior part, the vertebral or neural arch. The vertebral arch consists of a pair of pedicles and a pair of laminae and supports the articular, transverse and spinal processes. The body is the largest part of the vertebra and is composed of cancellous bone covered by a thin outer layer of cortical bone. The proximal and distal cortical layers are called the proximal and distal endplates respectively; and the anterior and posterior cortical layers are called the anterior and posterior wall respectively. The arches and processes projecting from the body are composed predominantly of cortical bone.

In a vertebral compression fracture, the bone of the vertebral body collapses. This may be caused by a trauma, osteoporosis, or other diseases, such as cancer. Vertebroplasty and balloon vertebroplasty (Kyphoplasty) are recent procedures to treat the pain associated with vertebral compression fractures due to osteoporosis. Vertebroplasty is an image-guided minimally invasive therapy used to stabilize and strengthen collapsed vertebral bodies and involves the injection of a bone cement, such as polymethylmethacrylate (PMMA) or a calcium phosphate cement, into the involved vertebral body under pressure. Although vertebroplasty has been successful in reducing or eliminating fracture pain and preventing further collapse, it does not correct the spinal deformation. In addition, vertebroplasty requires high-

pressure cement injections using low-viscosity cement which may lead to cement leaks, potentially resulting in damage to the spinal cord and nerve roots.

Balloon vertebroplasty (also referred to as Kyphoplasty) involves the initial insertion of two inflatable balloons into the vertebral body through the pedicles to expand the vertebral body and to create a cavity, whereafter the balloons are removed and bone cement is injected into the cavity. Since the purpose of the balloons is, predominantly, to correct the proximal or distal endplate, it is required to place the balloons under the most impressed part of the endplate. Until now, optimal positioning of the balloons has not always been feasible due to the offset and angulation of the drilled passage and the flexibility of the balloons, making reliable guidance difficult. A further drawback is that the balloons are filled with (and expanded by) a radiopaque fluid for visualization. In order to reduce the fracture (i.e. to reposition the collapsed bone to its original position), contrast fluid is forced in the balloons thereby increasingly obscuring parts of the field of interest in the vertebral body. This problem is worsened when the balloons are not evenly aligned, as is often the case because of the initial placement inaccuracy, in the lateral fluoroscopic line of view. Sometimes the balloons have to be deflated to restore the visibility of the operation area which can be accompanied by a spontaneous repositioning of the balloons and a loss of reduction.

Loss of reduction is also of concern in the interval between deflation and removal of the balloons and the setting of the injected bone cement. It is thus frequently observed that during the time interval between removal of the balloons and injection of the bone cement the reduction achieved by the inflation of the balloons is partially lost again.

Additionally, even after the injection of the cement there is a risk of collapse of the fracture during the period in which the cement has not yet cured. If the reduced fracture collapses while the cement did not have enough time to achieve adequate compression resistance (depending on multiple variables, this interval is between 30 and 240 minutes), the cement may be forced in unwanted directions (e.g. to the spinal cord), which is a serious complication that may lead to reoperation. In addition, the several steps of positioning and removing the balloon and subsequently filling the cavity formed with fill material are associated with an increased risk of infections.

In the case of traumatic vertebral fractures, various surgical strategies, such as anterior, posterior or combined stabilization, are available. Posterior stabilization using pedicle screw constructs has gained popularity over the last decade. Several studies, however, have reported on complications of this treatment such as failure of the instrumentation during the (late) postoperative period and/or recurrent kyphosis after removal of the instrumentation.

Accordingly, there is a continuing need for improved medical devices for treating, stabilizing and/or fixating fractured and/or collapsed bone.

The object of the present invention is to provide such a medical device by which the above drawbacks are obviated.

The present invention thus provides an expandable implant for treating fractured and/or collapsed bone, comprising a tube carrying an expansion member comprising expansion means for expanding the implant and creating a cavity, wherein said tube comprises at least one outlet for discharging a fill material within the created cavity, said implant comprising means for converting an axial movement of

said tube relative to the expansion member in a controlled transverse movement of the expansion means.

The expandable implant according to the invention is in particular suitable for treating vertebral body fractures. After insertion of the implant within the collapsed vertebral body, the expansion means are expanded by axially moving the tube relative to the expansion member, thus forming a cavity within the collapsed bone. The mechanism of converting an axial movement in a tranverse movement may be compared to the well-known mechanism found in an umbrella. After expansion of the implant, a fill material can directly be injected into the cavity, i.e. the device does not have to be removed prior to injection of the fill material. By creating the cavity within the bone, the implant according to the invention thus provides an access route for the fill material, while simultaneously maintaining an optimal reduction of the bone deformation during setting of the fill material. In contrast, as explained above, in balloon vertebroplasty a considerable amount of reduction is lost since the intradiscal pressure and muscle tension force the fracture towards the initial unreduced position directly after removal of the balloons. Moreover, as the expandable implant according to the invention does not have to be removed prior to injection of the fill material and thus forms an integral part of the reinforced bone after filling the cavity and setting of the fill material, the physiological properties of the fractured vertebral body are restored and a reliable three-dimensional stability is provided.

In a preferred embodiment of the invention the expansion member comprises at least one pair of elongate expansion means, located on opposite sides of the tube and which in unexpanded state are aligned parallel to the tube, said expansion means having a first end and a second end,

wherein the first end is mounted to a sleeve surrounding said tube and the second end is mounted to the tube, such that the central portion of the elongate expansion means expands transversally to the tube by axially moving the tube relative to said sleeve. The implant is inserted in unexpanded state, such that a relatively small passage through skin and bone is needed, thus minimizing damage to the bone and overlying tissues. Once in place within the collapsed bone, the implant is expanded, thereby displacing the fractured and collapsed bone and forming a cavity, which is then filled with the fill material which is directly injected through the tube and the outlets within the cavity.

The implant of the present invention can easily be applied and manipulated by the treating surgeon, i.e. the degree of expansion can be easily controlled by gently moving the tube relative to the expansion member. In addition, by positioning the expansion means on opposite sides of the rod a substantially unidirectional expansion is achieved, i.e. a vertical expansion in the case of a vertebral body fracture, thus preventing unwanted displacement of fractured bone pieces in the direction of the spinal cord.

According to a further preferred embodiment of the invention, the implant further comprises locking means for fixating the expansion means in an expanded state. By fixating the expansion means in expanded state collapsing of the expandable means, for example caused by intradiscal pressure is prevented.

Although the implant principally does not have to be removed after creating the cavity, it may in some situations be desired to relieve the expanded state of the implant, for example to be able to safely and easily remove the implant from the bone or to reposition the implant in case the implant may dislocate to a dangerous position. According to a

preferred embodiment, the implant therefore further comprises means for unlocking the expansion means, such that the expansion of the implant is reversible.

Preferably, the locking means comprise one or more recesses and one or more cooperating protrusions in the tube and the inside of the sleeve. By providing several recesses, it is possible to adjust the size of the expanded implant to the desired size of the cavity to be formed.

According to a further preferred embodiment of the invention, the elongate expansion means are flexible strips. Thus, sufficient contact between the bone tissue and the expansion means is ensured in order to be able to displace the bone tissue. According to another preferred embodiment of the invention, the elongate expansion means are flexible wires. Such flexible wires are easily mountable to the sleeve and easily expandable.

The implant according to the present invention may be implanted by a percutaneous and transpedicular approach to minimize damage to healthy tissue. Alternatively, if necessary, the implant may be implanted by open surgery, either transpedicularly or via an alternative posterolateral or anterior approach. Manipulation of the implant is simple and will necessitate only a short learning curve for the attending surgeon.

It will be understood that the implant may be made of any suitable biocompatible material, which is preferably visible with fluoroscopic or conventional radiological imaging under all circumstances. Preferably, the material is also MRI compatible to allow for detailed undistorted imaging of the fracture post-operatively and during follow-up. Suitable materials include stainless steel, titanium, cobalt-chromium or various alloys comprising these metals, polymers,

such as polymers based upon polyethylene, polymethyl-methacrylate, Tefon, Dacron or carbon fibres.

The expandable implant of the present invention may be used to treat different types of fractures, such as, but not limited to, osteoporotic vertebral fractures as well as traumatic vertebral fractures or vertebral collapse caused by diseases, such as cancer. In addition, the implant may be used in posterior interbody fusion procedures, and for treating bone fractures other than of the vertebra, such as tibial plateau fractures and distal radius fractures, calcaneus fractures and for femoral head collapse treatment.

The present invention further relates to an application device for applying the expandable implant as described above within the fractured and/or collapsed bone, comprising connection means for detachably holding the implant, means for reversibly expanding the implant, and filling means for providing the fill material.

For inserting the implant into the fractured and/or collapsed bone the implant is attached to the application device such that the implant is fixated relative to the application device. The implant is then inserted via a drilled passage through the cortical bone. Once in the correct position, the implant is expanded by realizing an axial movement of the tube of the implant relative to the expansion member. After the desired degree of expansion is achieved a fill material is injected through the tube by the filling means of the application device, and the implant is detached from the application device.

According to a preferred embodiment the application device further comprises orientation means for accurately holding the implant. Thus, a proper positioning of the implant within the fractured bone is ensured, which may not always be clearly visible by the used visualization

techniques. For example, in case of the vertebral body it is important that the implant is positioned within the vertebral body such that the expansion means do not expand in the direction of the spinal cord, but expand vertically in order to lift the endplate.

The invention is further illustrated by the following figures, showing a number of preferred embodiments of the implant according to the invention.

Figure 1 shows a perspective view of a preferred embodiment of the expandable implant according to the invention in unexpanded state (A) and expanded state (B).

Figure 2 shows a perspective view of another preferred embodiment of the implant in unexpanded state (A) and expanded state (B).

Figure 3 shows a perspective view of another embodiment of the the implant according to the invention in unexpanded state (A) and expanded state (B).

Figure 4 shows a perspective view of a vertebra, wherein an implant according to the invention has been inserted (lateral view).

Figure 5 shows a perspective view of a vertebra comprising two implants of the invention (view from above).

Figure 6 shows a schematic representation of two vertebra, wherein the implant according to the invention has been positioned between the two vertebra, i.e. intervertebrally.

Figure 7 schematically shows the subsequent steps of attaching the implant of figure 2 to the application device of which a preferred embodiment is shown, expanding the implant and releasing the implant from the application device.

According to the embodiment shown in figure 1, the implant 1 comprises a tube 2 having a central bore 3 and

outlets 4 near the end of the tube for discharging a fill material within the cavity formed by the expandable implant within the fractured bone. The fill material may be any appropriate material for injecting into the cavity formed, such as polymethyl-methacrylate bone cement or calcium phosphate bone cement or BMP's with appropriate carriers, autograft and/or allograft bone tissue etc. The tube 2 carries an expansion member 5 comprising a pair of elongate flexible strips 6 located on opposite sides of the tube and having a first end 7 and a second end 8. In unexpanded state (A) the strips 6 are aligned parallel to the tube 2 thus occupying a relatively small volume.

The first end 7 of the strips 6 has been mounted to a sleeve 9 surrounding the tube 2, while the second end 8 has been mounted to the tube 2. The central portion of the elongate members 6 thus expand transversally to the tube 2 by axially moving the tube 2 relative to the sleeve 9 (Fig. 1B).

As shown in Figure 1, the implant further comprises locking means for fixating the expansion means in an expanded state in order to prevent unwanted collapsing of the expansion means. The locking means comprise several recesses 10 in the tube 2, forming a rack at one side of the tube 2, and a cooperating protrusion 11 inside the sleeve 9. The expansion member 5 is rotatably mounted to the tube 2 for unlocking. The tube thus can rotate around its longitudinal axis independent of the expansion member 5.

The mechanism by which the sleeve 9 is moved over the tube in the embodiment shown in figure 1 thus resembles the mechanism found in a rivet gun. At the inside of the sleeve 9 is a latch 11 that cooperates with the recesses 10 forming the rack on the rod. When the tube 2 is axially moved relative to the expansion member the expansion member is locked by the cooperation of the latch and the recesses. Only

after rotating the tube at least 90 degrees relative to the expansion member 5, the latch 11 will become unlocked and the sleeve 9 can be moved back. By rotating the tube back to the original postion the locking mechanism is enabled again. Thus, the expansion of the implant is reversible and can easilly be controlled.

The relative movement of the sleeve 9 towards the end of the tube forces the flexible strips 6 in the curved position that is shown in Fig. 1B, that is, the central part of the strips expands transversally to the longitudinal axis of the tube, thereby displacing the collapsed bone and creating a cavity. The rack and latch mechanism holds the expandable strips in place after final positioning, and allows for changing the size of the formed cavity. The central bore 3 connected to the outlets 4 of the tube allows cement to be injected within the cavity. Thus, reinforced bone can be formed without any loss of reduction.

As shown in figure 2, the elongate expandable members may also comprise several pairs of flexible wires 12, which are easily connectable to the tube 2 and to the sleeve 9. As shown in this figure three pairs of flexible wires may be used, for example for use in seriously unstable bone fractures. The flexible wires are positioned on opposite sides of the tube 2 such the implant substantially expands in one direction (i.e. vertically in the case of a vertebral body fracture).

As shown in figure 3, the implant according to the invention may also comprise a tube 2, having a central bore and an outlet 4, wherein the expansion member 5 comprises a pair of jaws 13. By axially moving the tube 2 relative to the expansion member 5 via the screw thread 24 which is provided on the tube 2, the jaws, having a recess 19 of which the depth varies over the length of the jaw, are expanded by the

ball 14 which is mounted to the end of the tube 2. The means for converting an axial movement of the tube relative to the expansion member in a transverse movement of the expansion means in this embodiment thus comprise the ball 14 in cooperation with the recess 19 in the jaws.

Figure 4 and 5 show the implant 1 of the invention positioned and expanded within a typical vertebral body 15. Generally, the percutaneous and transpedicular insertion of the implant will be achieved by the following steps. First, a bilateral paramedian stab incision of the skin is performed followed by blunt muscle dissection using increasing diameter dilators. The largest dilator will subsequently function as a cannula. The entrance of the pedicle will be identified by fluoroscopy and pierced with an orthopaedic awl. The last step will be to use a small diameter hand drill to create space in the vertebral body. The implant can subsequently be implanted through the created pathway from skin to vertebral body. As shown in Figure 5 generally two implants 1 are inserted in the collapsed vertebral body 15 through a transpedicular canal 16. In case the length of the implant appears to be too long after inserting the implant, part of the tube 2 extending from the vertebra may be cut off.

As shown in Figure 6 the implant of the invention may also be used as an interbody device for anterior support in interbody fusion procedures. One or more implants 1 can for instance be introduced through a posterolateral approach into the disc space between two adjacent vertebra 15 where it is expanded and can at the same time be used as a delivery system for substances that accelerate and/or support interbody fusion such as calcium phosphate cements, allo- or autologous bone grafts and derivatives, or growth factors such as BMP's, in order to achieve anterior support and interbody fusion.

Figure 7 schematically show the steps of attaching the implant of figure 2 to the application device, expanding the implant to create a cavity within the fractured and/or collapsed bone and releasing the implant from the application device.

The implant 1 is held in the application device 20 by cooperation of the recesses 17 of the tube 2 and the protrusions 18 of the application device 20. The tube 2 of the implant is subsequently moved in the direction of the arrow by pulling the handle 25 (Fig. 7B). The implant is herewith fixated in the application device by means of a pair of pins 21 on the application device which are received in the corresponding holes 22 in the sleeve 9 of the implant (Fig. 7C). These pins 21 simultaneously function as orientation means in order to ensure that the implant is properly orientated.

After the implant has been inserted and positioned within the collapsed bone, the implant is expanded by pulling the tube 2 in the direction of the arrow, that is by achieving an axial movement of the tube 2 relative to the expansion member 5, whereby the expansion means expand (as shown in Fig 7D). In case the implant for example dislocates to a dangerous position the expansion may be reversed by achieving a rotation of the tube 2 relative to the expansion means 5 (as explained above) by means of rotating the handle 25 of the application device 20. As a final step, after forming the cavity a bone cement is injected within the cavity and the implant 1 is detached from the application device 20 (Fig 7E). As shown in Fig. 7E, the application device further comprises a bore 27 for providing the fill material. In addition the application device may further comprise a grip 26 for holding and manipulating the application device.

CLAIMS

1. Expandable implant for treating fractured and/or collapsed bone, comprising a tube carrying an expansion member comprising expansion means for expanding the implant and creating a cavity, wherein said tube comprises at least one outlet for discharging a fill material within the created cavity, said implant comprising means for converting an axial movement of said tube relative to the expansion member in a controlled transverse movement of the expansion means.

2. Implant as claimed in claim 1, wherein the expansion member comprises at least one pair of elongate expansion means, which in unexpanded state are aligned parallel to the tube, said expansion means having a first end and a second end, wherein the first end is mounted to a sleeve surrounding said tube and the second end is mounted to the tube, such that the central portion of the elongate expansion means expands transversally to the tube by axially moving the tube relative to said sleeve.

3. Implant as claimed in claim 1 or 2, further comprising locking means for fixating the expansion means in an expanded state.

4. Implant as claimed in claim 3, further comprising means for unlocking the expansion means.

5. Implant as claimed in claim 3, wherein the locking means comprise one or more recesses and one or more cooperating protrusions in the tube and the inside of the sleeve.

6. Implant as claimed in any of the claim 1-5, wherein the elongate expansion means are flexible wires.

7. Implant as claimed in any of the claims 1-5, wherein the elongate expansion means are flexible strips.

8. Application device for applying an implant as claimed in any of claims 1-7 within the fractured and/or collapsed bone, comprising holding means for detachably connecting the implant to the application device, means for reversibly expanding the implant and filling means for providing the fill material.

9. Application device as claimed in claim 8, further comprising orientation means for accurately positioning the implant within the device.

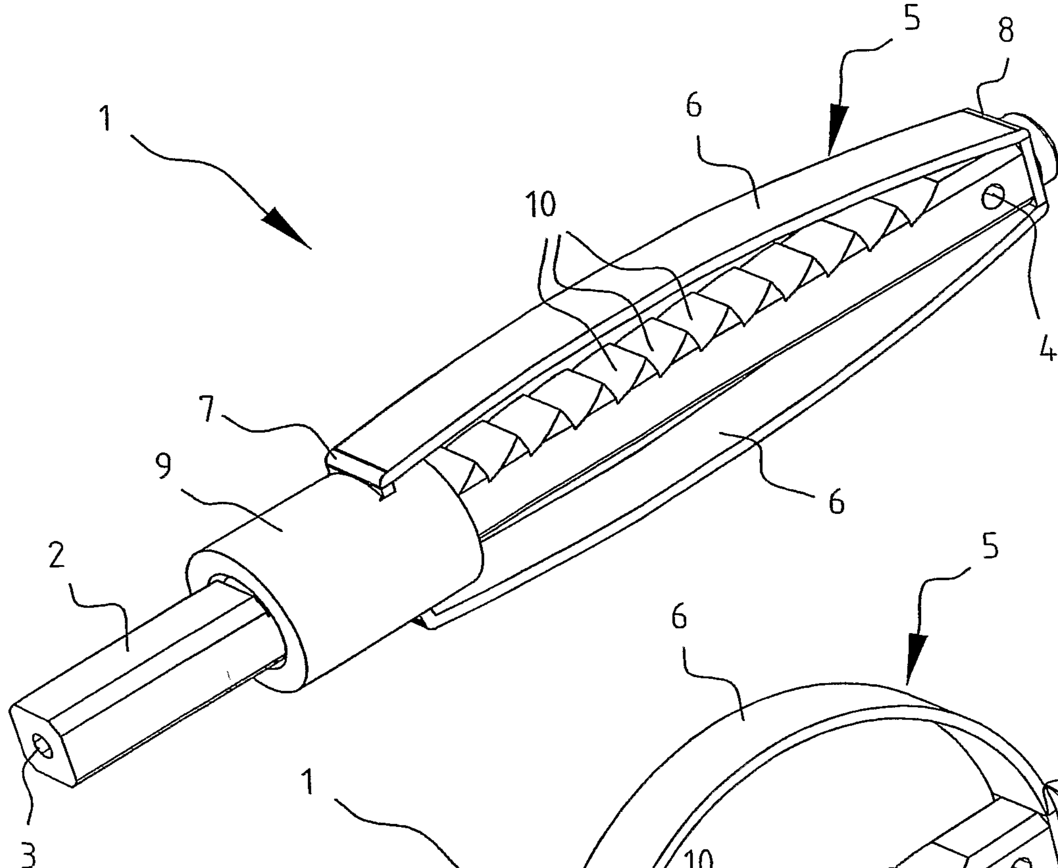

FIG. 1A

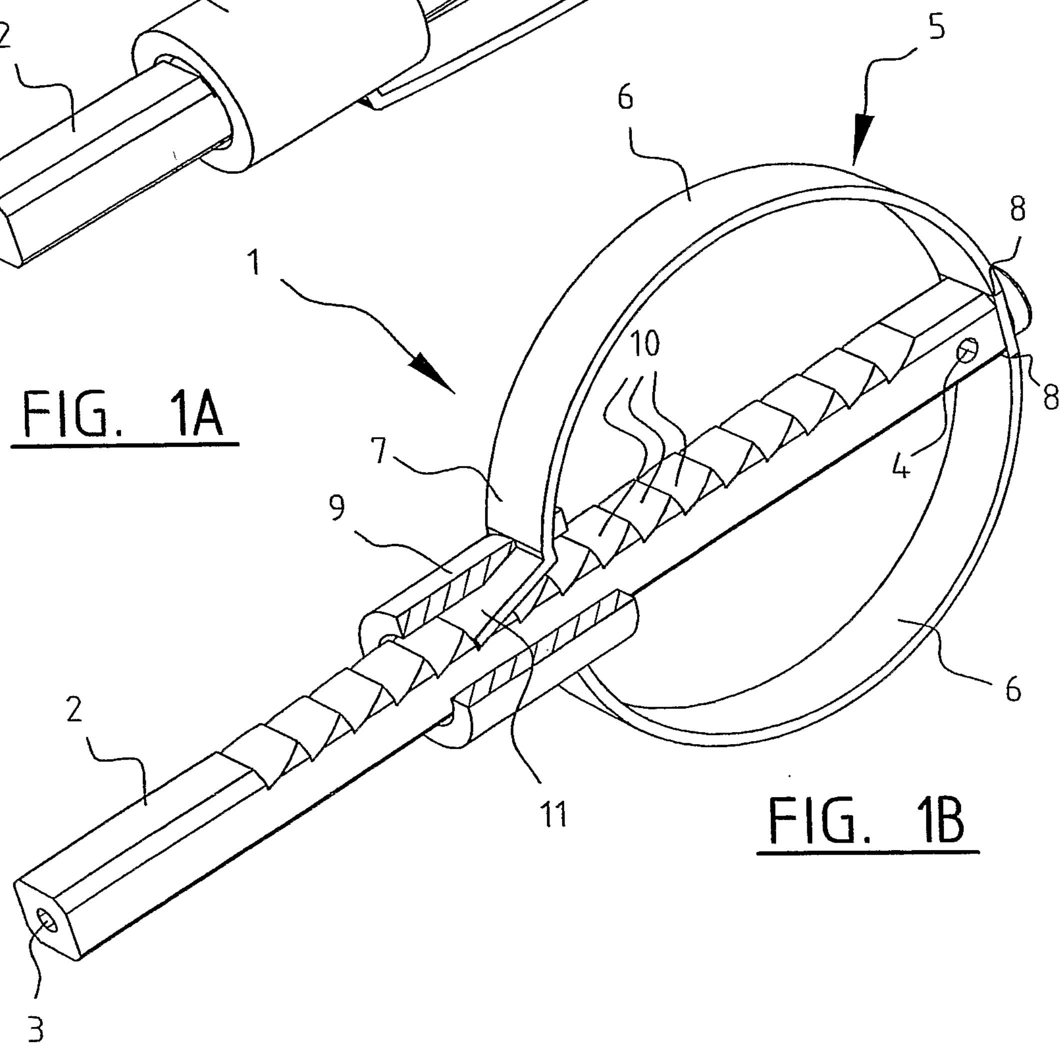

FIG. 1B

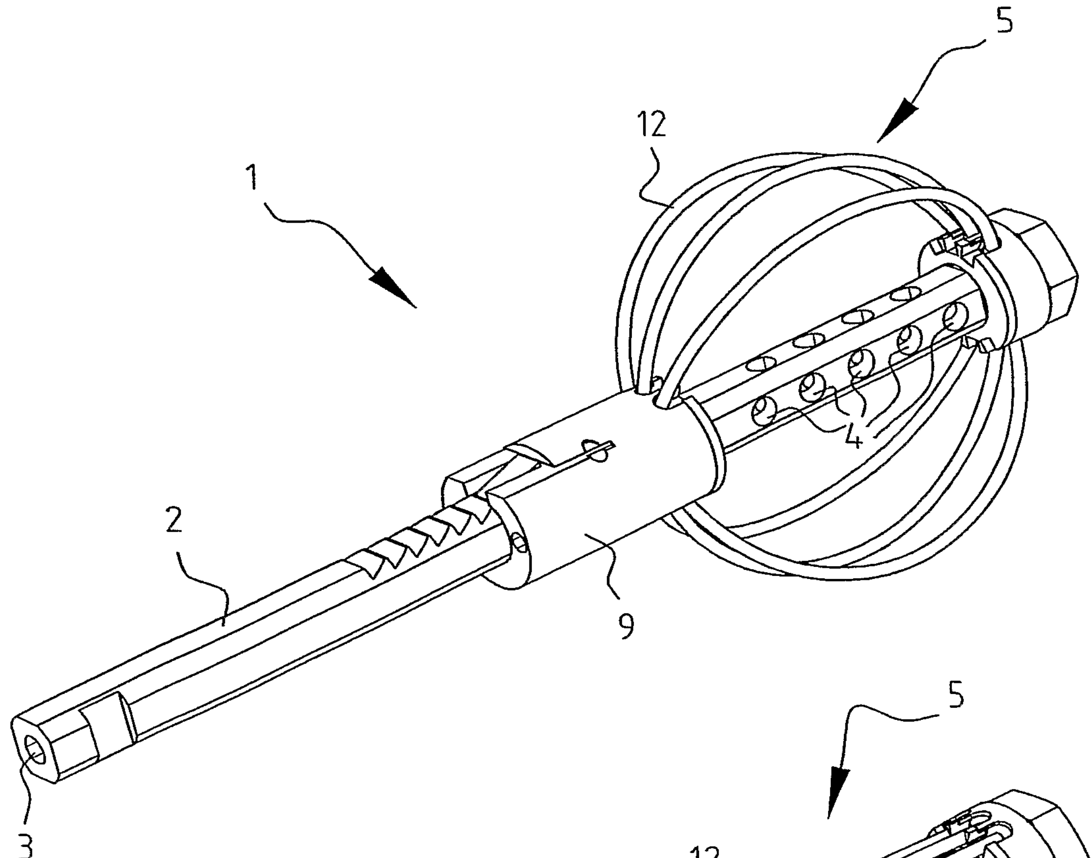

FIG. 2B

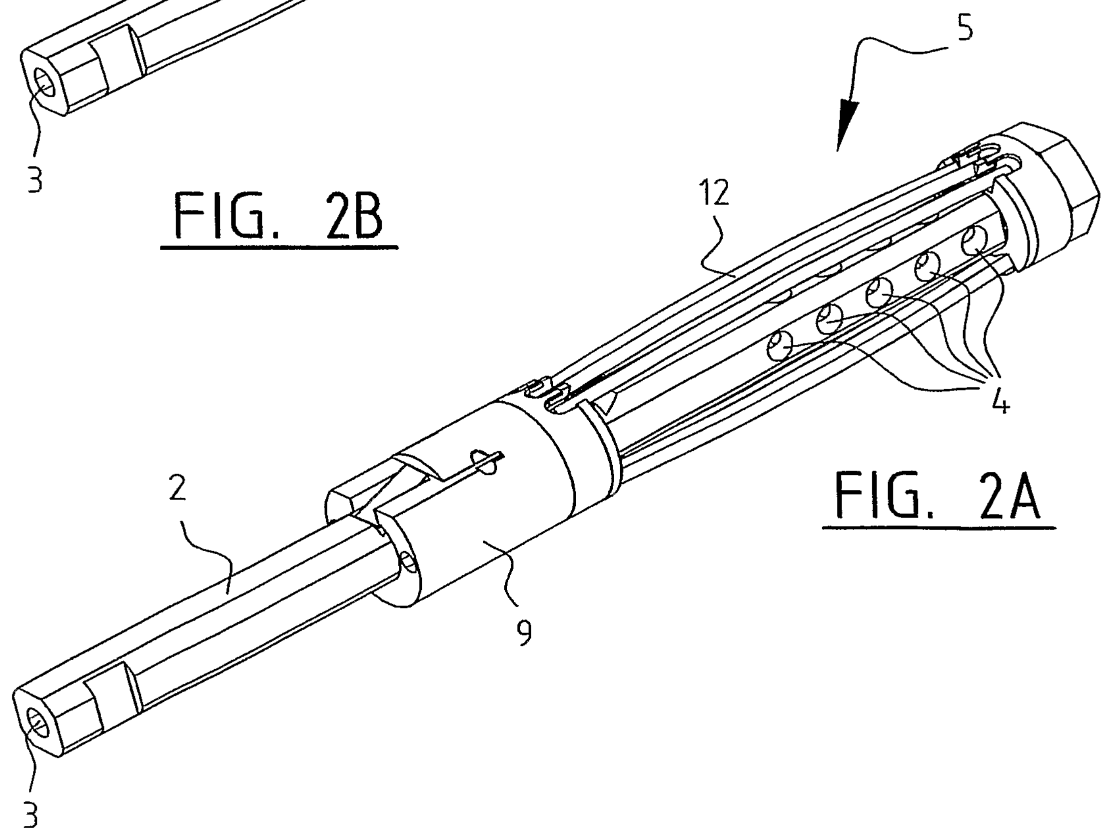

FIG. 2A

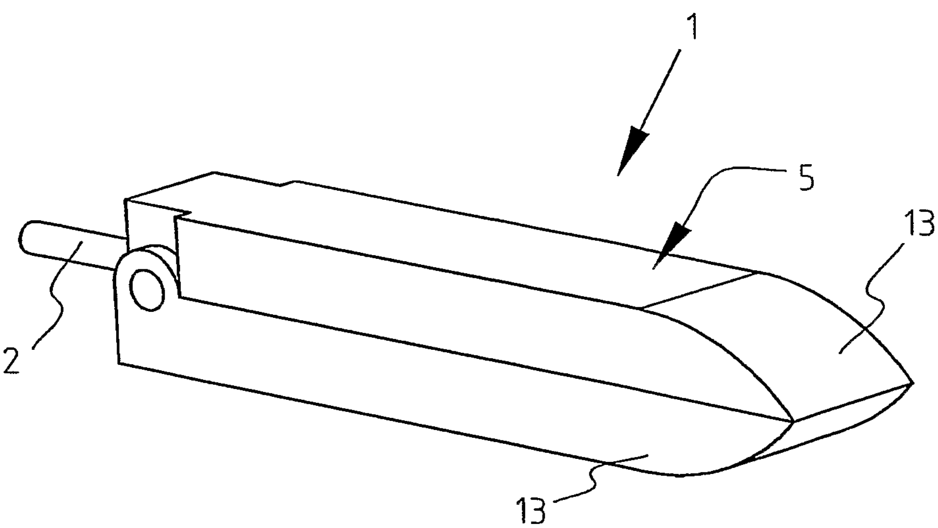

FIG. 3A

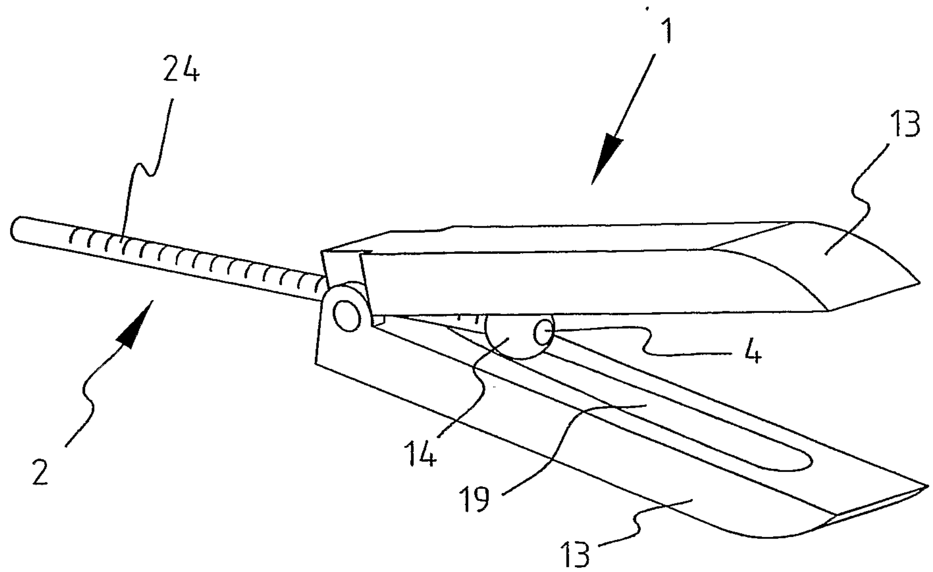

FIG. 3B

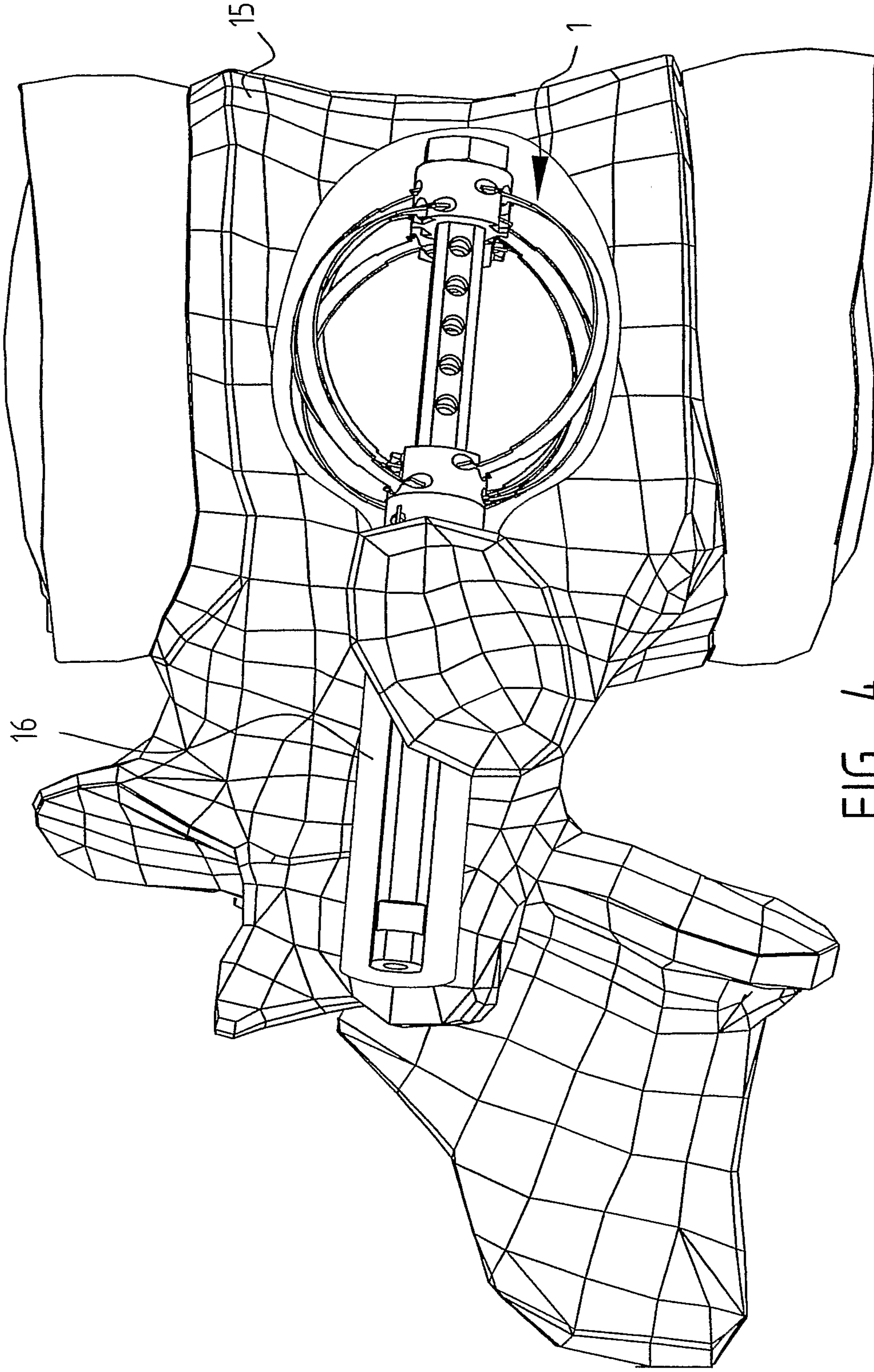

FIG. 4

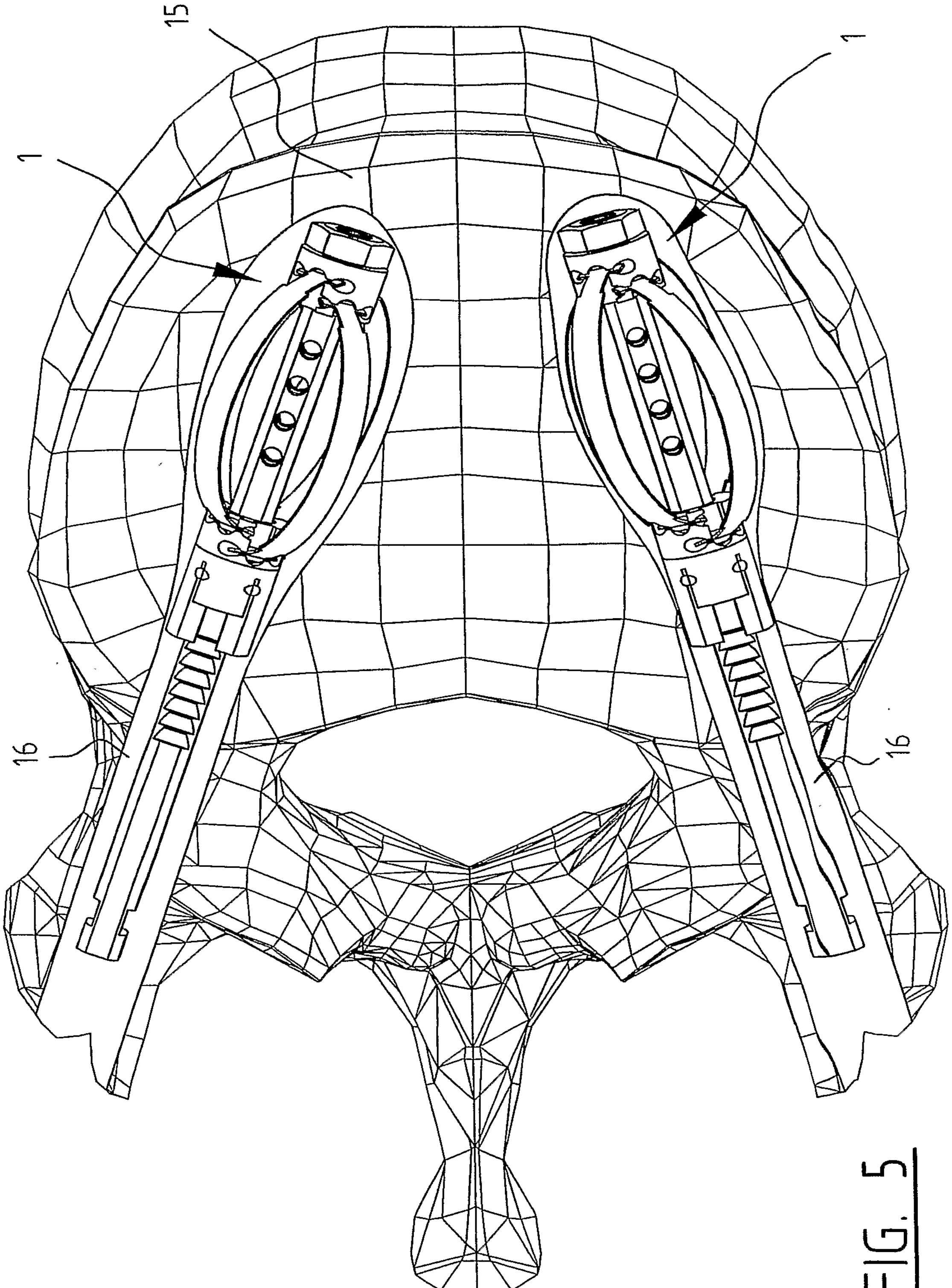

FIG. 5

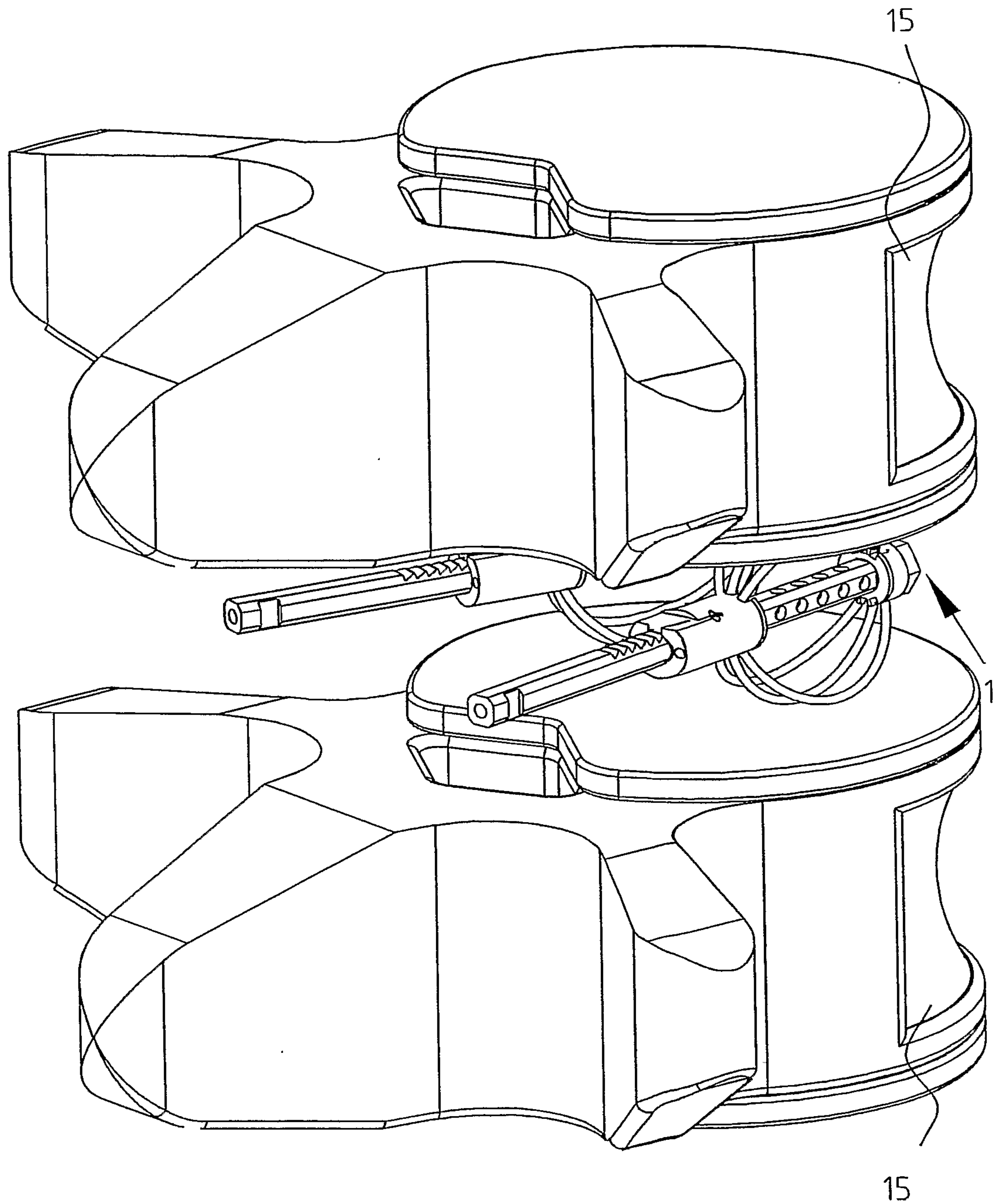

FIG. 6

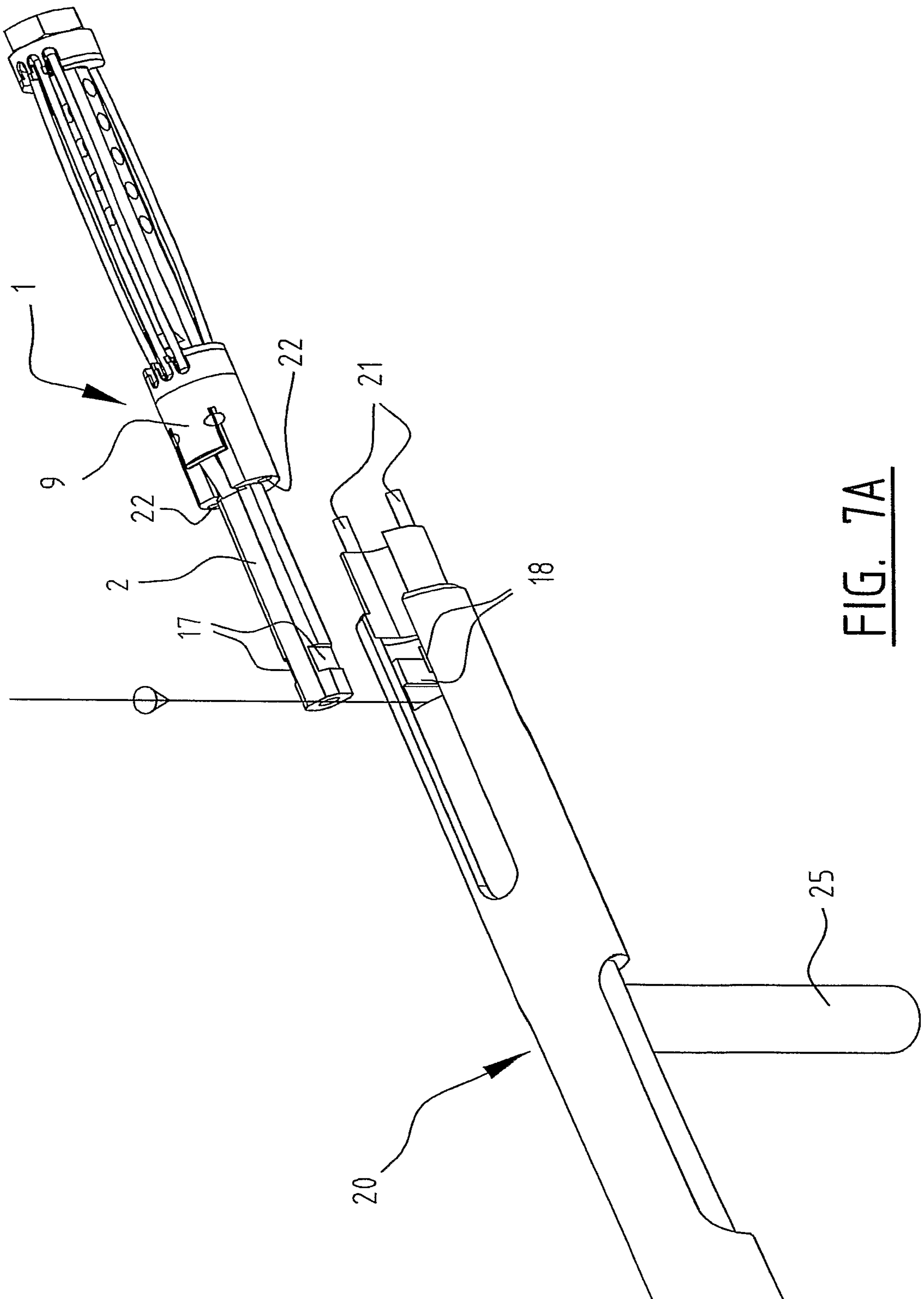

FIG. 7A

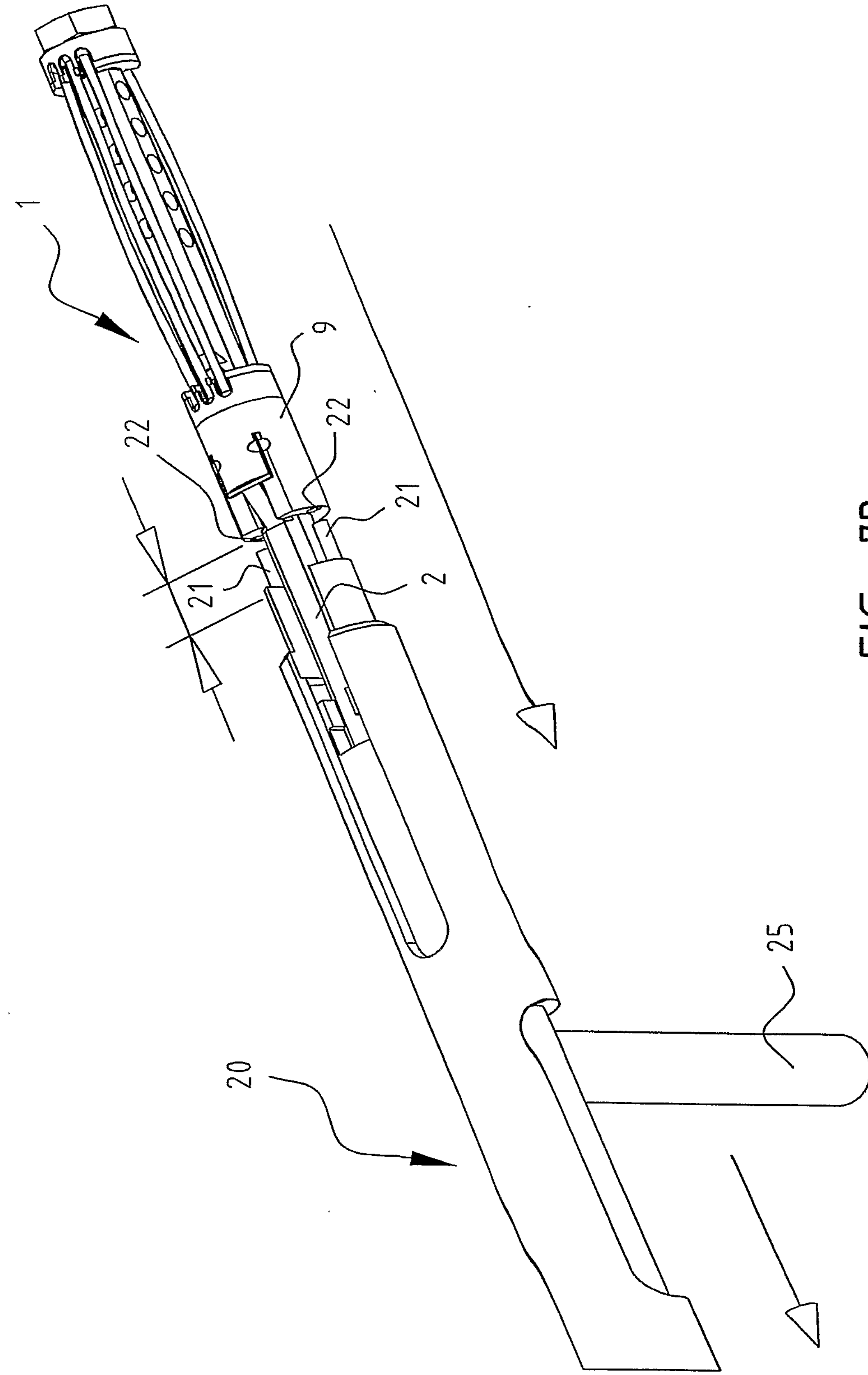

FIG. 7B

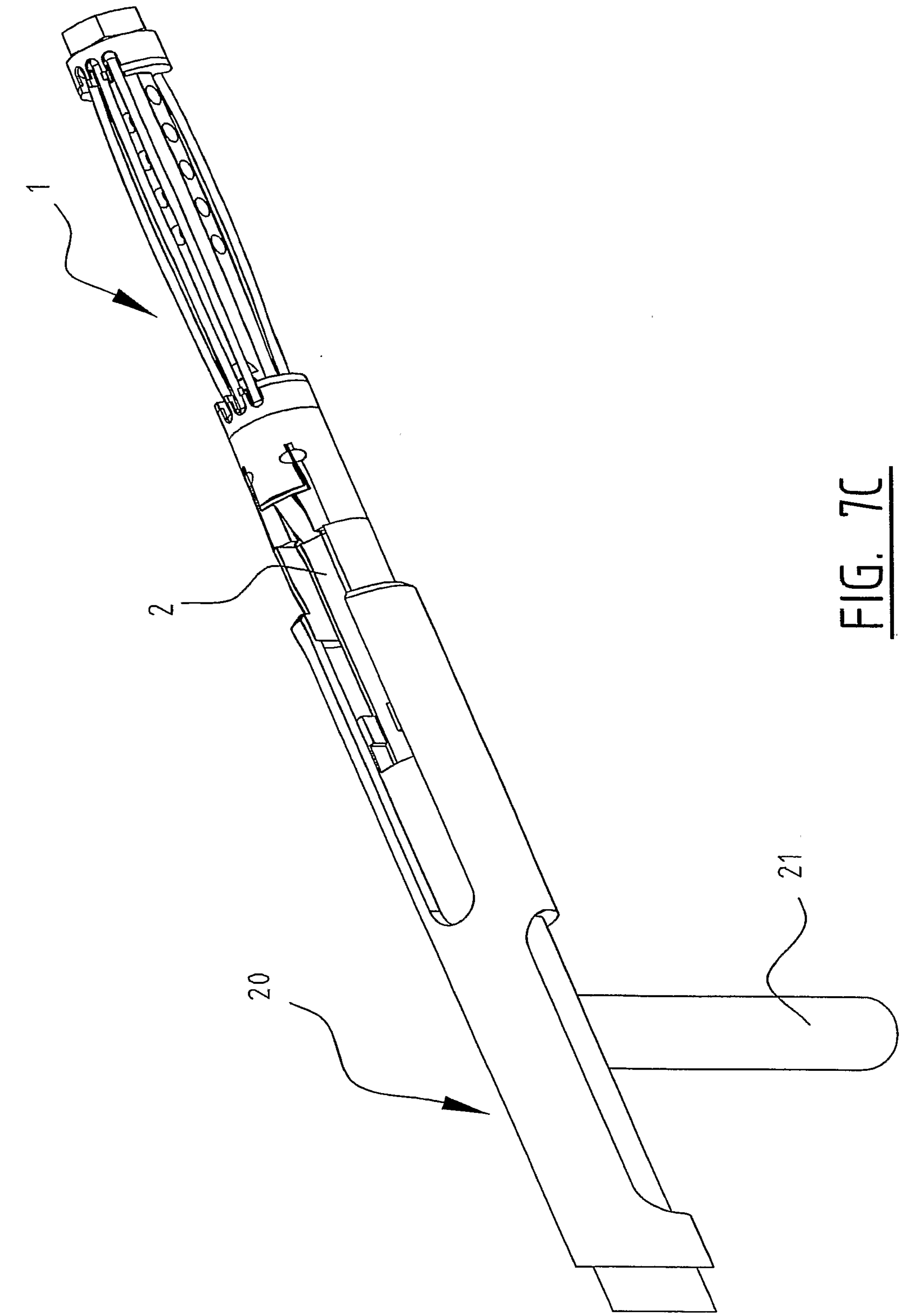

FIG. 7C

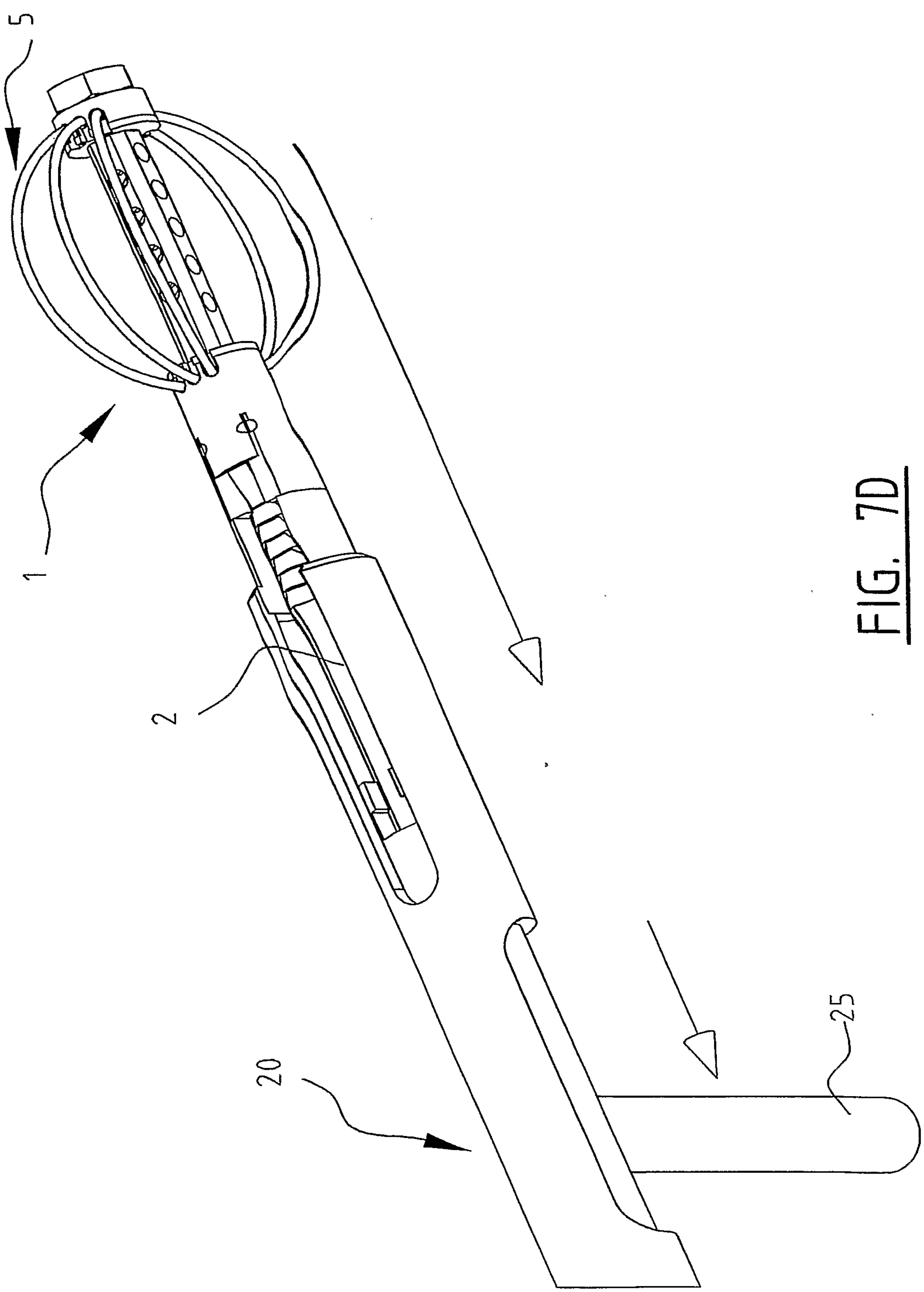

FIG. 7D

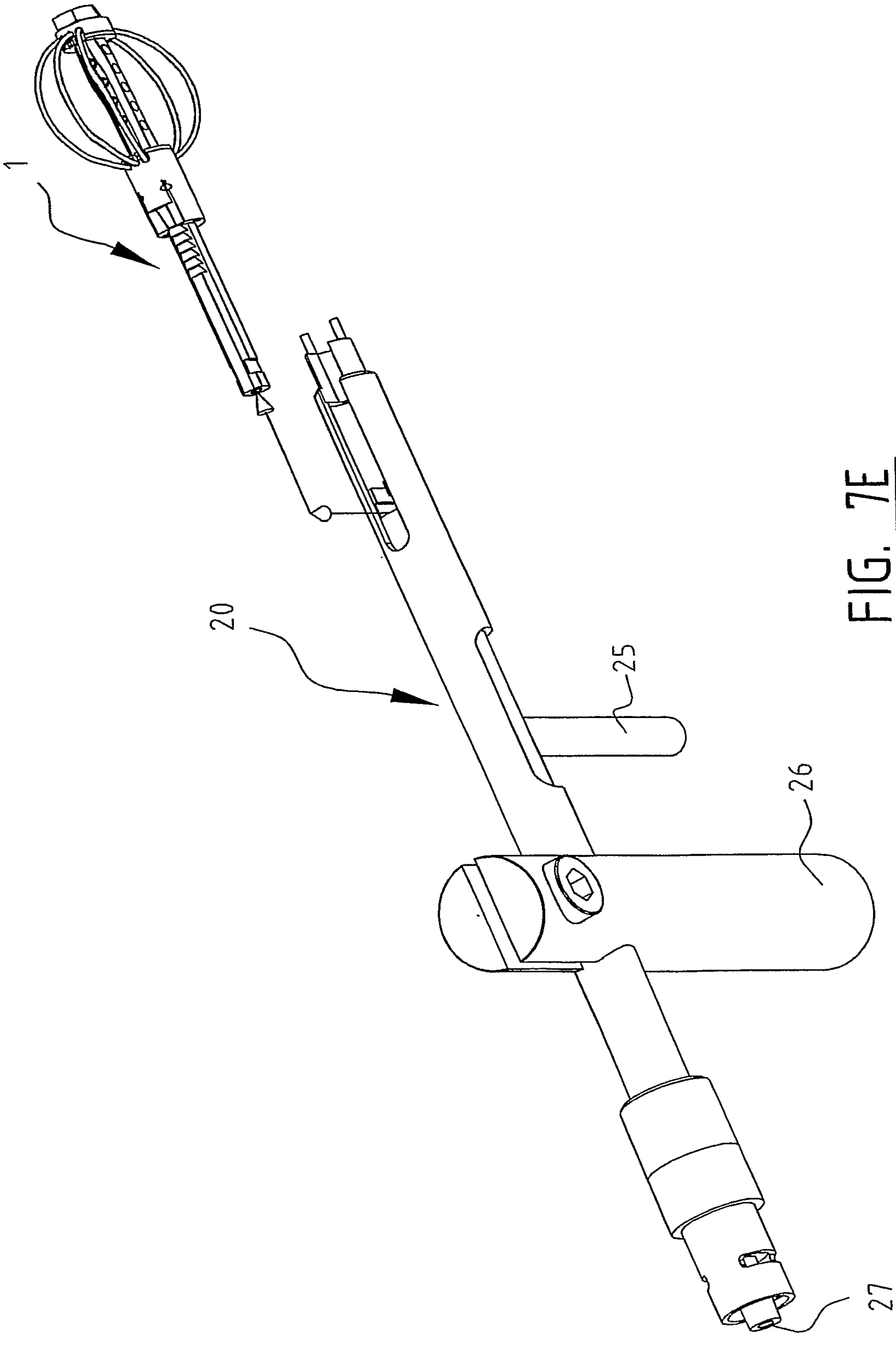

FIG. 7E

INTERNATIONAL SEARCH REPORT

International Application No
PCT/EP 03/12518

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61B17/58 A61B17/17

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 6 607 544 B1 (SCRIBNER ROBERT M ET AL) 19 August 2003 (2003-08-19) Expandable preformed structures for deployment in interior body regions. column 3, line 14 - column 4, line 9 column 13, line 46 - line 64 figures 3,6-9	1
X	US 5 972 015 A (SCRIBNER ROBERT M ET AL) 26 October 1999 (1999-10-26) Devices intended for deployment into interior body regions employ a catheter tube. column 3, line 1 - line 12 column 5, line 52 - column 6, line 67	1
X	WO 02/43628 A (SABITZER RONALD J ; FUSS FRANZ K (AT)) 6 June 2002 (2002-06-06) the whole document	1

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

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Date of the actual completion of the international search	Date of mailing of the international search report
15 July 2004	23/07/2004

Name and mailing address of the ISA	Authorized officer
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INTERNATIONAL SEARCH REPORT

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